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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,867	09/19/2003	Ann Marie Schmidt	55873-BA-PCT-US/JPW/AJM/A	6756

7590 06/29/2005

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EXAMINER

EMCH, GREGORY S

ART UNIT PAPER NUMBER

1649

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/665,867	<b>Applicant(s)</b> SCHMIDT ET AL.	
	<b>Examiner</b> Gregory S. Emch	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/29/2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,15,17-19 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,15,17-19 and 23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Formal Matters***

Claims 3, 5-14, 20-22, 24-69 were cancelled in a Preliminary Amendment filed 9/29/2003. Claims 1-2, 4, 15, 17-19, and 23 are pending and under consideration.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2 and 15 are drawn to an isolated EN-RAGE peptide, classified in class 530, subclass 324, for example.
- II. Claim 4 is drawn to an isolated nucleic acid molecule encoding EN-RAGE peptide classified in class 536, subclass 23.5, for example.
- III. Claim 17 is drawn to an antibody immunoreactive with an epitope comprising a unique sequence of EN-RAGE, classified in class 530, subclass 387.1, for example.
- IV. Claim 18 is drawn to drawn to a ribozyme which is capable of specifically cleaving EN- RAGE mRNA in a cell, classified in class 536, subclass 23.2, for example.
- V. Claims 19 and 23 are drawn to a transgenic nonhuman mammal whose germ or somatic cells contain a nucleic acid molecule which encodes EN-RAGE peptide introduced into the mammal or an ancestor at an embryonic stage, classified in class 800, subclass 21, for example.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I-V are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The EN-RAGE protein of Invention I can be used other than to make the antibody of Invention III. For example, said protein can be used as a probe or as a therapeutic or diagnostic agent (e.g. in screening). The nucleic acid of Invention II can be used to make a hybridization probe or can be used in gene therapy as well as in the production of EN-RAGE protein. Although the antibody of Invention III can be used to obtain the nucleic acid of Invention II, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically. The ribozyme of Invention IV can be used to inhibit the expression of mRNA, and the transgenic nonhuman mammal of Invention V can be used to produce large quantities of the protein of interest; however, they are structurally and functionally different each from the other and each from Inventions I-III. A search of any of the above Inventions would not necessarily reveal art to any other Invention.

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Because these Inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

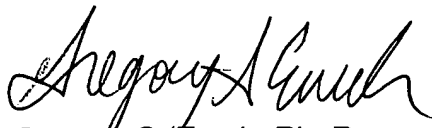
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***Advisory Information***

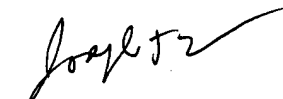
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 8:30AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached at (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gregory S. Emch, Ph. D.  
Patent Examiner  
Art Unit 1646  
June 23, 2005



**JOSEPH MURPHY  
PATENT EXAMINER**